U.S. DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

6:15-cv-1071

JOHN J. SIRACUSA **Plaintiff**	*	**CIVIL ACTION**
	*	
	*	
	*	**NUMBER:**
VERSUS	*	
	*	
BOEHRINGER INGELHEIM	*	**JUDGE:**
PHARMACEUTICALS, INC and	*	
BOEHRINGER INGELHEIM	*	
INTERNATIONAL GMBH	*	**MAGISTRATE:**
Defendants	*	
	*	

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COMPLAINT

Plaintiff, John J. Siracusa, (herein after "Plaintiff") by and through Plaintiff's attorneys, brings this action for personal injuries against Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH, (collectively, "Boehringer Ingelheim" or "Defendants"). Plaintiff alleges as follows:

PARTIES

1. At all times relevant hereto, the Plaintiff, John J. Siracusa, was a resident and citizen of Morgan City, Louisiana, located in St. Mary Parish.

2. Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") is a Delaware corporation, which has its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877 and may be served through its registered agent for service of process, CT Corporation System, 208 LaSalle, Suite 814, Chicago, Illinois 60604. Boehringer has conducted business and derived substantial revenue from within the State of Louisiana

3. Boehringer Ingelheim International GmbH ("Boehringer International") is a foreign corporation with its principal place of business located at Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rheine, Germany. Boehringer International has transacted and conducted business within the State of Louisiana. Boehringer International has derived substantial revenue from goods and products disseminated and used in the State of Louisiana, and Boehringer International expected or should have expected their acts to have consequences within the State of Louisiana.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the Plaintiff resides.

5. The Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

6. Venue of the case is proper in the Western District of Louisiana pursuant to 28 U.S.C. § 1391(b)(1) because all Defendants are residents of this state.

7. Venue is further proper in this Court pursuant to 28 U.S.C. § 1391, because a substantial part of the events giving rise to Plaintiff's claim occurred, in part, in the Western District of Louisiana.

STATEMENT OF FACTS

8. At all relevant times, Defendants, directly and through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Pradaxa® (dabigatran etexilate).

9. Pradaxa® is a direct thrombin inhibitor that is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Patients with atrial fibrillation have an increased risk of stroke.

10. Pradaxa® was approved by the Food and Drug Administration ("FDA") on October 19, 2010. The FDA approved two dosages: 75 mg and 150 mg, to be taken twice daily. Pradaxa® was the first anticoagulation medication approved in the U.S. in more than 50 years for patients with non-valvular atrial fibrillation.

11. Prior to the FDA's approval of Pradaxa®, warfarin was the only oral anticoagulation medication available in the U.S. for reducing stroke and systemic embolism in patients with non-valvular atrial fibrillation. Unlike patients who use Pradaxa®, users of warfarin must follow dietary restrictions and must regularly monitor their blood levels (INR) by undergoing blood tests and potentially adjusting the dose of their medication.

12. Defendants promoted Pradaxa® as a novel medicine for patients with non-valvular atrial fibrillation. Defendants' marketing campaign for Pradaxa® included promoting it as being more effective than warfarin in preventing strokes and systemic embolism, providing a convenient alternative to warfarin therapy because it does not require blood monitoring or dose adjustments, and does not require any dietary restrictions.

13. Defendants spent significant money in promoting Pradaxa®, which included $67,000,000.00 spent during 2010 (although Pradaxa® was not approved for sale until October 19, 2012).[1]

14. During 2011, Defendants reportedly undertook 1.5 million Pradaxa® "detailing sessions" (marketing/sales visits by Defendants' sales force) with U.S. primary care physicians,

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[1] Deborah Weinstein, *Study: Sales Support is Dwindling, Not Dead*, March 14, 2012, **Medical Marketing and Media.**

internists, group practitioners, cardiologists, and practice nurses, spending approximately $464,000,000.00 during this 12 month period to promote Pradaxa® in the United States.[2]

15. As part of their marketing of Pradaxa®, Defendants widely disseminated direct-to-consumer advertising campaigns that were designed to influence patients to make inquiries to their prescribing physician about Pradaxa® and/or request prescriptions for Pradaxa®.

16. In the course of these direct-to-consumer advertisements, Defendants overstated the efficacy of Pradaxa® with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa®, and that such irreversibility could have permanently-disabling, life-threatening and fatal consequences.

17. At all times relevant to this action, The Pradaxa® Medication Guide, prepared and distributed by Defendants and intended for U.S. patients whom Pradaxa® has been prescribed, failed to warn and disclose to patients that there is no agent to reverse the side effects of Pradaxa® and that if serious bleeding occurs, it may be irreversible, permanently disabling and life-threatening.

18. From October 2010 until the end of March 2011, approximately 272,119 prescriptions for Pradaxa® were written in the United States. During that same period, there were 932 Pradaxa®-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the U.S. Food and Drug Administration, including at least 120 deaths and over 500 reports of severe, life-threating bleeding.

19. From April 1 through the end of June 2011, there were an additional 856 Pradaxa®-associated "SAE" Medwatch reports filed with the U.S. Food and Drug

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[2] Id.

Administration, including at least 117 deaths and over 510 reports of severe, life-threatening bleeding.

20. During the Defendants' 2011 fiscal year, worldwide Pradaxa® sales eclipsed the $1 billion threshold, achieving what is commonly known in the pharmaceutical industry as "blockbuster" sales status.[3]

21. Defendants' original labeling and prescribing information for Pradaxa®:

a. failed to disclose in the "Warning" section that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa®;

b. failed to advise prescribing physicians, such as Plaintiff's physician, to instruct patients that there was no agent to reverse the anticoagulation effects of Pradaxa®;

c. failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

d. failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;

e. failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa®;

f. failed to warn that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®;

g. failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa®;

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[3] Heide Oberhauser-Aslam and Tapan Sharma, *Boehringer Sees Sales Rising Further as 2011 Profits Surge*, April 24, 2012, **WSJ.com**.

h. failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Pradaxa®;

i. failed to provide adequate warnings and information related to the increased risk of bleeding events associated with the aging patient populations of Pradaxa® users;

j. failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Pradaxa®, especially, in those patients with a prior history of gastrointestinal issues and/or upset;

k. failed to include a **"BOXED WARNING"** about serious bleeding events associated with Pradaxa®;

l. failed to include a **"BOLDED WARNING"** about serious bleeding events associated with Pradaxa®;

m. in their "Medication Guide" intended for distribution to patients to whom Pradaxa® has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences;

n. failed to provide adequate warnings regarding the risk of fall with aging patients; and

o. failed to provide adequate warnings regarding the risk of cerebral infarction.

22. During March of 2011, Defendants modified the U.S. labeling and prescribing information for Pradaxa® which included additional information regarding the use of Pradaxa®

in patients taking certain medications. Despite being aware of: (I) serious, sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) almost 1800 SAE Medwatch reports filed with the U.S. Food and Drug Administration, including at least 237 deaths and over 1,000 reports of severe, life-threatening bleeding, defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in the previous paragraph.

23. On July 1, 2011, Pradaxa® was approved for sale in New Zealand with lower dosing (lowered from 150 mg to 110mg twice a day) required for patients over 80 years of age and recommended for patients with moderate renal impairment.

24. On July 25, 2011, the Archives of Internal Medicine published *The Use of Dabigatran* [Pradaxa®] *in Elderly Patients*. [Vol 171, No. 14] which concluded that "The risk of major over dosage of… [Pradaxa®] in this [elderly] population is, however, much increased owing to frequent renal function impairment, low body weight, drug interactions that cannot be detected with a routine coagulation test and no antagonist available."

25. On January 21, 2011, Pradaxa® (under the brand name Prazaza®, in 75 mg and 110 mg doses only), was approved for sale in Japan to treat non-valvular atrial fibrillation.

26. On August 11, 2011, Japan's pharmaceutical regulatory authority announced that it was requiring a **"BOXED WARNING"** be added to Pradaxa® (marketed a Prazaza® in Japan) to call attention to reports of severe hemorrhages in patients treated with Pradaxa® (Prazaza®).

27. On September 1, 2011, the New Zealand pharmaceutical regulatory authority issued a "Prescriber Update" entitled "Dabigatran – Is There a Bleeding Risk" in which physicians were alerted that Pradaxa® had a higher incidence of gastrointestinal bleeds than warfarin and that there was no reversal agent to neutralize the anticoagulation effects of

Pradaxa®. A follow-up report issued on December 2011, indicated that among 10,000 New Zealanders who had taken Pradaxa®, there were 78 reports of serious bleeding events associated with Pradaxa® including 60 reports of gastrointestinal and rectal bleeding. Among the 78 serious events were 10 patient deaths and 55 hospitalizations. Three months later, in March of 2012, the New England Journal of Medicine published two letters from physicians in New Zealand addressing bleeding events associated with Pradaxa®. In one letter, physicians wrote, "We are concerned that the potential risks of this medication are not generally appreciated. The serious consequences of a lack of an effective reversal agent should not be underestimated."

28. During November 2011, Defendants modified the U.S. labeling and prescribing information for Pradaxa® adding additional information regarding the use of Pradaxa® in patients with kidney disease. Despite being aware of: (i) serious, sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the *Archives of Internal Medicine*; (iii) the addition of a **"BOXED WARNING"** to Pradaxa® in Japan; and (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 21.

29. On December 7, 2011, the U.S. Food and Drug Administration issued a Drug Safety Communication announcing that it was undertaking a "Drug Safety Review" of Post-Marketing Reports of Serious Bleeding Events with the anticoagulant Pradaxa®. The purpose of the FDA's review is to determine if serious bleeding events associated with the use of Pradaxa® are more common that expected based on the Defendants' data submitted to the FDA.

30. As of December 31, 2011, the U.S. Food and Drug Administration received over 500 reports of deaths of people in the U.S. linked to Pradaxa® which, at that point, had been

available in the U.S. for approximately 14 months. In addition, there were over 900 reports of gastrointestinal hemorrhages, over 300 reports of rectal hemorrhages, and over 200 reports of cerebrovascular accidents suffered by U.S. citizens associated with Pradaxa®.

31. In January 2012, Defendants modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the *Archives of Internal Medicine*; (iii) the addition of a **"BOXED WARNING"** to Pradaxa® in Japan; (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®; and (v) the Drug Safety Communication published by the FDA in December 2011, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 21.

32. During March 2012, in response to a directive from Health Canada, the governmental agency responsible for regulating pharmaceuticals in Canada, the Defendants' Canadian affiliate issued a "Dear Healthcare Provider" letter in which it advised Canadian healthcare providers of certain risks associated with the use of Pradaxa® (marketed as Pradaxa® in Canada) in elderly patients and patients with impaired kidney function and prosthetic heart valves. No such similar communication was sent to healthcare providers in the United States.

33. In April 2012, the Defendants modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the *Archives of Internal Medicine*; (iii) the addition of a **"BOXED WARNING"** to Pradaxa® in Japan; (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®; (v) the Drug Safety Communication published by the FDA in

December 2011; and (vi) the "Dear Healthcare Provider" letter Defendants were required to provide in Canada, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 21.

34. At all times relevant hereto, Defendants failed to warn emergency room doctors, surgeons and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding that occurs in the presence of warfarin, there is no effective agent to reverse the anticoagulation effects of Pradaxa® and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Pradaxa®.

PLAINTIFF'S USE OF PRADAXA® AND RESULTING INJURIES

35. As a result of Defendants' claims regarding the effectiveness, safety, and benefits of Pradaxa®, the plaintiff, John Siracusa, was unaware and could not have reasonably known or learned through reasonable diligence that he would be exposed to the risk of excessive and/or uncontrollable bleeding and other injuries described herein.

36. Therefore, John Siracusa was prescribed Pradaxa® on or around February 13, 2013, upon discretion of his physician for atrial fibrillation, in order to receive cardioversion.

37. On March 14, 2013, John Siracusa presented to the Teche Regional Medical Center in Morgan City, Louisiana with black, tarry stool associated with fatigue and weakness, which he had been experiencing consistently for three days.

38. Plaintiff was admitted to the hospital on such date and administered five units of packed red blood to combat his symptoms.

39. During Plaintiff's hospital stay, Mr. Siracusa's physician recommended he discontinue using Pradaxa® for the foreseeable future.

40. John Siracusa was discharged from Teche Regional Medical Center on March 15, 2013.

41. Prior to John Siracusa's use of Pradaxa®, Defendants knew or should have known that the original labeling of the drug did not adequately warn Plaintiff, or persons similarly situated, of the risks associated with using the drug as described above.

42. Prior to John Siracusa's use of Pradaxa®, Defendants knew or should have known of the defective nature of Pradaxa® and persons who were prescribed and ingested Pradaxa® for even a brief period of time, including John Siracusa, were at increased risk for developing life threatening injures and side effects. Defendants, through their affirmative misrepresentations and omissions, concealed from Plaintiff the true and significant risks associated with Pradaxa® use.

43. Plaintiff was unaware of the increased risk for developing life-threatening injuries as compared to warfarin. Had Plaintiff known of the risks and dangers associated with Pradaxa®, as well as the lack of additional benefits, and had Defendants provided adequate warnings to reserve the side effects of Pradaxa®, John Siracusa would not have used Pradaxa®.

44. As a direct and proximate result of using Pradaxa®, Plaintiff suffered severe injuries, physical pain, and mental anguish.

CAUSES OF ACTION

COUNT I:

STRICT LIABILITY – FAILURE TO WARN: L.A. R.S. 9:2800.57

45. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

46. At all times relevant to this suit, Defendant engaged in the business of designing, manufacturing, testing, marketing, labeling, and placing into the stream of commerce, Pradaxa®, for sale to, and use by, members of the public.

47. At all times relevant to this suit, the dangerous propensities of Pradaxa® were known to Defendants, or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective product to physicians who would be expected to prescribe the drug for their patients.

46. The Pradaxa® manufactured by Defendants reached John Siracusa without substantial change and was ingested as directed.

47. Defendants marketed Pradaxa® in multiple ways, including but not limited to direct-to-consumer advertisements, which were misleading in that Defendants overstated the safety and efficacy of Pradaxa® and understated its risk.

48. The Pradaxa® was defective and unreasonably dangerous in that the labeling was insufficient to warn users of the side effects associated with using the drug.

49. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the fired, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks of irreversible bleeds and other injuries and death associated with the use of Pradaxa® were inadequate.

50. By failing to provide Plaintiff and Plaintiff's physician with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with

exposure to Pradaxa®, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

50. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously and/or intentionally disregarded Plaintiff and Plaintiff's rights, and as a result, Plaintiff sustained serious injuries.

COUNT II:

STRICT PRODUCTS LIABILITY – DESIGN DEFECT, MARKETING DEFECT, CONSTRUCTION OR COMPOSITION DEFECT & MANUFACTURING DEFECT: LA. R.S. 9:2800.55 AND 9:2800.56

50. Plaintiffs hereby incorporated by reference all preceding paragraphs as if fully set forth herein.

51. Defendants are the manufacturers, designers, distributors, sellers and suppliers of Pradaxa®, who sold Pradaxa® in the course of business.

52. The Pradaxa® manufactured, designed, sold, marketed, distributed, supplied, and/or placed in the stream of commerce by Defendants was expected to and did reach the consumer without any alterations or changes.

53. The Pradaxa® administered to John Siracusa was defective in design or formulation in at least one of the following aspects:

a. When it left hands of the Defendants, this drug was unreasonably dangerous to an extent beyond that which could reasonably be contemplated by Plaintiff;

b. Any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended;

c. The dosages and/or formulation of Pradaxa® sold by Defendants were unreasonably dangerous;

d. There are no patients for whom the benefits of Pradaxa® outweighed the risks;

e. The product was not made in accordance with the Defendants' specifications or performance standards;

f. There are no patients for whom Pradaxa® is a safer and more efficacious drug than other drug products in its class; and/or

g. There were safer alternatives that did not carry the same risks and dangers that Defendants' Pradaxa® had.

54. The Pradaxa® administered to Plaintiff was defective at the time it was distributed by the Defendants or their control.

55. The foreseeable risks associated with the design or formulation of Pradaxa® were more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or did not have the claimed benefits.

56. The defective and unreasonably dangerous design and marketing of Pradaxa® was a direct, proximate and producing cause of Plaintiff's injuries and damages. Under strict products liability theories set forth in the Restatement (Second) of Torts, Defendants are liable to Plaintiff for all damages claimed in this case, including punitive damages.

57. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Pradaxa®, Plaintiff was injured as described herein.

58. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Pradaxa®, Plaintiff was required to obtain reasonable and

necessary health care treatment and services and incurred expenses for which Plaintiff is entitled to damages.

COUNT III: NEGLIGENCE

59. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

60. Defendants owed a duty to the general public and specifically to John Siracusa to exercise reasonable care in the design, study, development, promotion, sale, labeling, marketing and distribution of Pradaxa® at issue in this lawsuit.

61. Defendants breached their duty and failed to exercise reasonable care in the developing, testing, and designing of Pradaxa®, because it was capable of causing serious injuries, such as those sustained by Plaintiff.

62. Defendants breached their duty and also failed to exercise reasonable care in the marketing of Pradaxa®, because they failed to warn, that as designed, Pradaxa® was capable of causing serious injuries, such as those sustained by Plaintiff.

63. Defendants breached their duty and also failed to exercise ordinary care in the labeling of Pradaxa® and failed to issue adequate warnings to consumers of the risks of serious bodily injury or death due to the use of Pradaxa®. Moreover, Defendants over-promoted the benefits of Pradaxa® in patients suffering from atrial fibrillation and understated the risks associated with the use of Pradaxa®.

64. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward John Siracusa:

a. In disseminating information to Plaintiff that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as John Siracusa;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Pradaxa®;

c. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent, and

d. In designing and placing into the stream of commerce a product that was unreasonably dangerous for its foreseeable use, which Defendant knew or should have known could cause injury to John Siracusa.

65. Despite the fact that Defendants knew or should have known that Pradaxa® posed a serious risk of bodily harm to consumers and/or did not provide any additional benefits, Defendants continued to manufacture and market Pradaxa® for use by consumers.

66. Defendants knew or should have known that consumers, including John Siracusa, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

67. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, labeling, and/or manufacturing of Pradaxa® was a proximate cause of John Siracusa's injuries.

68. Defendants' conduct, as described above, including, but not limited to its failure to adequately test Pradaxa®, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it

created, evidence actions and/or intentional disregard of the rights of John Siracusa, so as to warrant the imposition of punitive damages.

COUNT IV:

NEGLIGENT MISREPRESENTATION AND/OR FRAUD

69. Plaintiff hereby incorporates by reference all of the above allegations as if fully set forth herein.

70. Defendants represented that Pradaxa® was just as safe or safer and just as effective or more effective than other anticoagulation alternatives and had additional benefits compared to other anticoagulation medications available on the market.

71. Defendants made these misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Pradaxa® had defects, dangers, and characteristics that were other than what Defendants had represented to John Siracusa.

71. Specifically, Defendants misrepresented to and/or actively concealed from John Siracusa and other consumers, among other things, that:

a. Pradaxa® had statistically significant increases in irreversible bleeds and other side effects which could result in serious, permanent injury or death;

b. Pradaxa® had not been fully or adequately tested;

c. Pradaxa® does not have any known reversal agents;

d. Pradaxa® bleeds cannot be stopped or controlled by any effective medical processes or medical intervention; and

e. Pradaxa® was not as safe as blood thinners, such as warfarin.

72. Defendants negligently and/or intentionally misrepresented or omitted this information in their product labeling, promotions and advertisements and instead labeled, promoted and advertised their product as safer and more effective that other types of anticoagulation alternatives and understated the risk of excessive and/or uncontrollable bleeding associated with Pradaxa®.

73. The aforementioned misrepresentations were untrue and misleading.

74. Defendants knew or should have known that these representations were false and made representations with the intent that John Siracusa would rely on them, leading to the use of Pradaxa®.

75. At the time of Defendants' fraudulent misrepresentations, John Siracusa was unaware of the falsity of the statements being made and believed them to be true. John Siracusa justifiably relied on and/or was induced by the misrepresentations and/or active concealment and relied on the absence of safety information, which Defendants did suppress, conceal, or failed to disclose, to the detriment of John Siracusa.

76. As a direct and proximate result of the fraudulent act and omissions, suppression and misrepresentations of Defendants, John Siracusa suffered injuries.

77. Defendants' actions and omissions as identified in the Complaint demonstrate malicious actions and/or intentional disregard for John Siracusa's rights, so as to warrant the imposition of punitive damages.

COUNT V:

BREACH OF EXPRES WARRANTY

78. Plaintiffs incorporation by reference each preceding paragraph as though set forth fully at length herein.

79. Defendants expressly warranted, through their direct-to-consumer marketing, label, and sales representatives, that Pradaxa® was a safe and effective prescription blood thinner. The safety and efficacy of Pradaxa® constitute a material fact in connection with the marketing, promotion, and sale of Pradaxa®.

80. Pradaxa® manufactured and sold by Defendants did not conform to these express representations because it cause serious injury to consumers when taken in recommended dosages.

81. As a direct and proximate result of Defendants' breach of warranty, John Siracusa suffered bodily injury.

82. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions and/or intentional disregard of John Siracusa's rights so as to warrant the imposition of punitive damages.

COUNT VI:

PUNITIVE DAMAGES

95. Plaintiff hereby incorporates by references all of the above allegations as if fully set forth herein.

96. At all material times, the Defendants knew or should have known Pradaxa® was inherently dangerous.

97. Despite their knowledge, the Defendants continued to aggressively market Pradaxa® to consumers, including John Siracusa, without disclosing its dangerous side effects when there existed safer, alternative products.

98. Despite Defendants' knowledge of the defective and unreasonably dangerous nature of Pradaxa®, Defendants continued to test, design, develop, manufacture, label, package,

promote, park, sell and distribute it so as to maximize sales and profits at the expense of the health and safety of the public, including John Siracusa, in conscious disregard of the foreseeable harm caused by Pradaxa®.

100. Defendants' conduct was intentional and/or wanton.

101. Defendants' conduct as described above, including, but not limited to, their failure to adequately test their product, to provide adequate warnings, and their continued manufacture, sale and marketing of their products when they knew or should have known of the serious health risks created, evidence a flagrant disregard for human life as to warrant the imposition of punitive damages as the acts or omissions were committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Pain and suffering;
4. Punitive damages;
5. Pre-judgment interest at the lawful rate;
6. Attorneys' fees, expenses, cost of this action, and;
7. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on issues so triable.

Respectfully submitted,
/s/ Jules B. LeBlanc III
Jules B. LeBlanc III, #08201
14725 Villa Court
Baton Rouge, LA 70810
Email: jl3@cox.net

ATTORNEY FOR PLAINTIFF

JULES B LEBLANC III
14725 VILLA COURT DRIVE
BATON ROUGE LOUISIANA 70810

US District Court
800 Lafayette Street, Suite 2100
Lafayette Louisiana 70501

Attn: Amanda Brown

April 6, 2015

I appreciate your cooperation today in assisting me in filing the attached Lawsuit in the Western District of Louisiana in Lafayette, Louisiana. My client lives in Morgan City, Louisiana. Enclosed is my check for $400.00 for the filing fees.

I am a solo practioner with no legal secretary. I lost my right arm in an accident and I have Parkinson's disease therefore it would be very difficult for me to try to file electronically.

My bar roll # 8201

Very Truly Yours,

Jules B LeBlanc III

Jl3@cox.net O-225-768-7818 C-225-324-1135 F-225-761-8348